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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	SD-50003USP6	6174
23492 7590 06/30/2008 PAUL D. YASGER ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT 1611	PAPER NUMBER
			NOTIFICATION DATE 06/30/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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DETAILED ACTION

Receipt of amendment, remarks and terminal disclaimers all dated 4-8-08 and IDS dated 4-29-08 is acknowledged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-8-08 has been entered.

Status of Claims

Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are pending.

Examiner notes that the Remarks submitted with the above amendment states that claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are pending. However, the amendment presented on 4-8-08 canceled claims 34 and 40. It appears that the claim limitation "evening or at night" of previously presented claims 34 and 40 is now introduced into claim 29 and accordingly claims 34 and 40 have been canceled.

Claim Rejections - 35 USC § 112

2. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. A review of the instant specification on pages 6, lines 21-25, page 20, lines 3-16 and table II on page 31 reveals that the instant claim limitations “for achieving a balanced lipid alteration in a patient in need thereof”, “at least two formulations comprising” are not supported by the instant specification with respect to 500 mg and 1000 mg. In other words, while the new claim limitations are supported with at least two 750 mg formulations to achieve a daily dose of 1500 mg, the specification (at the above cited places) do not appear to support the at least two with respect to 500 mg and 1000 mg to achieve a daily dose of 1500 mg. Specifically, on page 20 of the specification it is stated that two tablets of 500 mg for a 1000 mg dose, two tablets of 750 mg for 1500 mg dose and 2 tablets of 1000 mg for a 2000 mg dose, which is not the same as that claimed i.e., “at least two intermediate release formulations comprising 500, 750 or 1000 mg of nicotinic acid and a swelling agent to obtain a dose of at least 1500 mg”. Further, the at least two tablet limitation on page 20 does not appear to be associated with the claimed “for achieving a balanced lipid alteration in a patient in need thereof”. Hence, the claims lack written description support.

3. In response to that amendment, the rejections previously of record have been withdrawn and the following new rejection has been applied to the pending claims:

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 29, 30, 32, 35-36, 38, 41-42, 44, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5260305 to Dennick in view of US 5268181 to O'Neil ('181).

6. Dennick teaches a combination of cholesterol lowering drugs that include niacin, of the instant claims, for effectively lowering cholesterol levels, such as LDL and for treating hyperlipemia (col. 2). Dennick teaches niacin in an amount ranging 75 mg to 2000 mg (col. 3, L 49-63), in a single or divided dosage forms. For the claimed swellable polymers, Dennick gelatin, starch etc (col. 4, L 37-40). While Dennick does not state 1500 mg in a single dose, the range of 75 -2000mg includes the claimed 1500 mg because Dennick teaches starting with a low dose and working up to higher concentrations so as to achieve a desired effect (col. 3, L 64-67). Thus, administering a dose of 1500 mg would have been within the scope of a skilled artisan with an expectation to achieve the desired treatment for elevated cholesterol levels. Dennick fails to teach administering at evening or night.

7. '181 teach a composition comprising niacin in an amount as high as 750 mg (see examples), for the treatment of hyperlipidemia (abstract, col. 2). The composition is administered in the evening similar to the instant claims. '181 teach the same delivery system as that described in the instant claims i.e., HPMC, magnesium stearate etc (see examples). '181 teach administering niacin composition in a single dose between 8 -10 pm, preferably at evening or bedtime (col. 2, L 35-55). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to administer the

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niacin composition of Kuhrts at evening or night suggested by '181, because '181 teaches that administering in the evening or at bedtime enables achieving niacin levels during the day when the levels are effective to substantially lower the levels of said serum lipids or lipid components which are primarily nocturnally biosynthesized. Hence a skilled artisan would have expected to achieve the balance of cholesterol levels without any associated side effects such as hepatotoxicity and yet a prolonged release of niacin.

The terminal disclaimers filed on 4-8-08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,080,428, 6,129,930, 6,469,035, 6,406,715, 6,746,691, 6,818,229 and 7,011,848 and application no. 10/444,145 have been received. The terminal disclaimers will be processed and Applicants will be notified in the next action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Lakshmi S Channavajjala/
Primary Examiner,
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June 23, 2008